

REMARKS

This application has been carefully reviewed in light of the Office Action dated May 28, 2008. Claims 1-3, 9-12 and 14 remain in this application. Claims 1-3 are the independent Claims. Claims 1-3 and 9-12 have been amended. Claims 4-8 and 13 are canceled without prejudice. It is believed that no new matter is involved in the amendments or arguments presented herein.

Reconsideration and entrance of the amendment in the application are respectfully requested.

Claim Objection

Claim 10 was objected to because of an informality. In response, Applicant has replaced that word with "surface." It is believed that the substitution addresses the concern of the above objection.

Reconsideration and withdrawal of the above objection are respectfully requested.

Art-Based Rejections

Claims 1-7, 13 and 14 were rejected under 35 U.S.C. § 102(b) over Canadian Patent No. 2389056 (Miyamoto); Claims 1-5, 7-9 and 13 under were rejected under 35 U.S.C. § 102(b) over U.S. Patent Publication No. 2002/0103526 (Steinke); Claims 1-6, 10, 11 and 13 were rejected under 35 U.S.C. § 102(b) over U.S. Patent Publication No. 2001/0046518 A1 (Sawhney); Claims 1-5 and 8-12 were rejected under 35 U.S.C. § 102(e) over U.S. Patent No. 6,890,904 (Wallner).

Applicant respectfully traverses the rejections and submits that the claims herein are patentable in light of the clarifying amendments above and the arguments below.

The Miyamoto et al. Reference

Miyamoto et al. is directed to a hydrogel having a cell growth factor (See, *Miyamoto*; Page 4, lines 16-18).

The Steinke Reference

Steinke is directed to a stent 5 with a protective coating 19 (See, *Steinke*; Abstract and Paragraph [0041]).

The Sawhney Reference

Sawhney is directed to the occlusion of arteriovenous malformations by the introduction of hydrogels by a catheter (See, *Sawhney*; Paragraphs [0073] and [0074]).

The Wallner et al. Reference

Wallner et al. is directed to a method of treating subjects with abnormal cell proliferation (See, *Wallner*; Abstract).

The Claims are Patentable Over the Cited References

The present application is generally directed to an embolization device.

As defined by amended independent Claim 1, an embolization device for embolizing a vessel cavity *in vivo* is provided. The embolization device is coated with a biological response modifier. The embolization device is a coil. A β (1 \rightarrow 3) glucan is applied by coating to a surface of the embolization device.

The applied references fail to disclose or suggest the above features of the claims of the present invention. In particular, the applied references fails to disclose or suggest "an embolization device for embolizing a vessel cavity *in vivo*, the embolization device coated with a biological response modifier (BRM), wherein the embolization device is a coil and wherein a β (1 \rightarrow 3) glucan is applied by coating to a surface of the

embolization device," as required by amended independent Claim 1 of the present invention.

Miyamoto discloses a hydrogel having a cell growth factor (*See, Miyamoto; Page 4, lines 16-18*). Miyamoto further merely teaches that the hydrogel may be used in combination with a coil made of platinum (*See, Miyamoto; Page 7, lines 22-26*). However, Miyamoto fails to disclose or suggest a hydrogel of β (1 \rightarrow 3) glucan applied by coating to a surface of the coil.

In contrast, the present invention requires the embolization device to be coated with a biological response modifier that is β (1 \rightarrow 3) glucan applied by coating to the surface of the embolization device. This feature promotes superior thrombus formation and organization around the embolization device after it has been placed (*See, Specification; Page 8, lines 12-18*).

Moreover, Steinke is directed to a stent 5 with a protective coating 19 dissolvable or degradable in blood to allow the stent to be deployed at an implantation site (*See, Steinke; Abstract and Paragraphs [0041] and [0044]*). Importantly, Steinke teaches that stents are provided to prevent re-closure of a vessel so as to maintain normal blood flow through a vessel. Therefore, a stent is a device provided to keep a vessel open. However, Applicant respectfully submits that one of ordinary skill would understand that an embolization device is a device to occlude a vessel, which is exactly opposite to keeping a vessel open. Therefore, a stent that keeps open a vessel clearly does not teach an embolization device that occludes a vessel. Thus, Applicant respectfully submits that the assertion on page 3 of the Office Action that the stent 5 discloses an embolization device is unreasonably broad and makes no sense.

Furthermore, the protective coating 19 can be formed of curdlan and chitosan. However, the protective coating 19 itself fails to teach an embolization device which is a coil for embolizing a vessel cavity, and at best, teaches a protective coating to protect the stent from damage during handling (*See, Steinke; Paragraph [0044] and [0047]*).

Furthermore, Applicant notes that there is no teaching or suggestion that the stent itself is coiled, only that the protective coating polymer wrapping the stent is coiled (*See, Steinke; Paragraph [0022]*).

In contrast, the present invention requires a coiled embolization device for embolizing a vessel that includes a β (1 \rightarrow 3) glucan applied by coating to a surface of the coiled embolization device. In this manner, an embolizing effect is achieved using the coiled embolization device and coating.

Moreover, Sawhney is directed to the occlusion of arteriovenous malformations using hydrogel in the form of a rod, pellet, fiber, etc. Paragraphs [0073] and [0074] merely teach that conventional embolic materials for endovascular treatment includes coils. Importantly, Sawhney teaches the introduction of hydrogel by catheter, and not by a coil with hydrogel. There is clearly no disclosure or suggestion that a coil is coated on the surface with Sawhney's hydrogel. Instead, in paragraphs [0086] and [0088], a hydrogel coating is provided to a stent, which as discussed above, holds a lumen open instead of closed and cannot be reasonably considered an embolization device. A stent is the opposite of an embolization device. Furthermore, Sawhney teaches the use of lentinan as an antitumor agent capable of being used with other agents.

In contrast, the present invention requires a coiled embolization device for embolizing a vessel that includes a β (1 \rightarrow 3) glucan applied by coating to a surface of the coiled embolization device.

Moreover, Wallner fails to disclose or suggest a coiled embolization device providing an occluding function. Instead, Wallner merely teaches in column 4, lines 19-29 and col. 16, lines 9-11 of direct needle injections and inhalation for treating abnormal cell proliferation. Wallner further teaches coatings and stents individually, but not embolization devices with coatings or even stents with coatings (*See, Wallner; Col. 25, line 53*). For at least the same reasons as discussed above, a stent is not an

embolization device. Furthermore, Lentinan and sizofiran applied by coating to a surface of an embolization device is clearly not disclosed or suggested.

In contrast, the present invention requires a coiled embolization device for embolizing a vessel that includes a β (1 \rightarrow 3) glucan applied by coating to a surface of the coiled embolization device.

Thus, the applied references do not disclose or suggest this feature of the present invention as required by amended independent Claim 1.

Since the applied references fail to disclose, teach or suggest the above features recited in amended independent Claim 1, those references cannot be said to anticipate nor render obvious the invention which is the subject matter of that claim.

Accordingly, amended independent Claim 1 is believed to be in condition for allowance and such allowance is respectfully requested.

Applicant respectfully submits that amended independent Claims 2 and 3 are allowable for at least the same reasons as discussed above with reference to amended independent Claim 1 and such allowance is respectfully requested.

The remaining claims depend either directly or indirectly from amended independent Claims 1-3 and recite additional features of the invention which are neither disclosed nor fairly suggested by the applied references and are therefore also believed to be in condition for allowance and such allowance is respectfully requested.

For example, with respect to dependent Claim 11, it is noted that those claims require "lentinan is applied by coating to a surface of the embolization device." However, Sawhney merely teaches a hydrogel plug for the delivery of antitumor agents such as lentinan. There is no disclosure or suggestion of drug delivery via the coil coated with lentinan for embolization. Therefore, this requirement further distinguishes the present application over Sawhney.

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Conclusion


In view of the foregoing, it is respectfully submitted that the application is in condition for allowance. Reexamination and reconsideration of the application, as amended, are requested.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is requested to call the undersigned attorney at the Los Angeles, California telephone number (310) 785-4721 to discuss the steps necessary for placing the application in condition for allowance.

If there are any fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-1314.

Respectfully submitted,
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